



1651
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vincent Fischetti et al.

Appl. No.: 10/067,979 Group Art Unit: 1651

Filing Date: February 8, 2002 Examiner: Prats, Francisco Chandler

Title: Therapeutic Treatment of Upper Respiratory Infections

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56 and 37 CFR §1.97**

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents is being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action that would be appropriate to antedate or otherwise remove as a competent reference any document that is determined to be a *prima facie* prior art reference against the claims of the present application.

The instant Information Disclosure Statement is being filed in compliance with 37 CFR §1.97(b) prior to the mailing date of the first official action, therefore, no fee is required in connection with its filing. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 08-1641.

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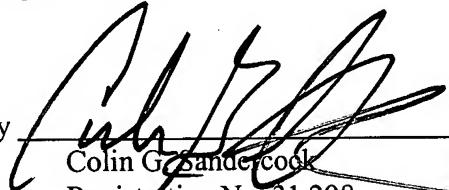
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Attached as Appendix A is a list of all patents and applications filed by the present inventive entity relating to phage associated lytic enzymes and their uses. The listed U.S. patents are cited in the attached form SB/08A.

Attached herewith as Appendices 1-6 are copies of International Search Reports received in PCT applications corresponding to applications listed in Appendix A. For the Examiner's convenience, the cover sheet and claims for each of the PCT applications are also provided.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

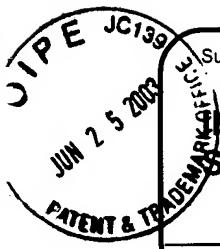
Respectfully submitted,

By 
Colin G. Sandcock
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Date: 6-25-03

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Sheet	1	of	11	Attorney Docket Number	

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
1	US- 6056954		05/02/00	Fischetti, et al.	
2	US- 5997862		12/07/99	Fischetti, et al.	
3	US- 5985271		11/16/99	Fischetti, et al.	
4	US- 5688501		11/18/97	Merril, et al.	
5	US- 4742981		05/10/88	Converse	
6	US- 2019789		11/05/35	Mahannah	
7	US- 2763931		09/25/56	McMillan	
8	US- 5479732		01/02/96	Burtsch, et al.	
9	US- 3465445		09/09/69	Fisher	
10	US- 2315260		03/30/43	Lancaster	
11	US- 5604109		02/18/97	Fischetti, et al.	
12	US- 5260292		11/09/93	Robinson, et al.	
13	US- 4957686		09/18/90	Norris	
14	US- 6017528		01/25/00	Fischetti, et al.	
15	US- 6132970		10/17/00	Stemmer	
16	US- 3852424		12/03/74	Gaeumann, et al.	
17	US- 6264945		07/24/01	Fischetti, et al.	
18	US- 6254866		07/03/01	Fischetti, et al.	
19	US- 6248324		06/19/01	Fischetti, et al.	
20	US- 6238661		05/29/01	Fischetti, et al.	

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)			
21	EP-0510907 A 2		10/28/92	Agricultural & Food Res.	
22	WO-9702351		01/23/97	CIBA Geigy AG, et al.	
23	WO-9607329		03/14/96	Univ. Maryland	
24	WO-9904809		02/04/99	Ambo, Inc.	
25	FR-2357246		02/03/78	Martinez	
26	WO-9531562		11/23/95	Quest International B.V.	
27	EP-587541 A1		03/16/94	Tecnogen ScpA	

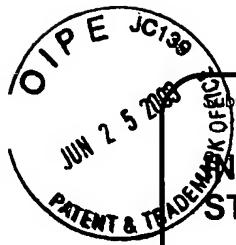
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Complete if Known	
Application Number	10/067,979
Filing Date	2/8/02
First Named Inventor	Vincent Fischetti
Group Art Unit	1651
Examiner Name	PRATS, FRANCISCO CHANDLER
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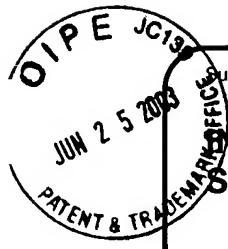
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28	US- 6056955		05/02/00	Fischetti, et al.	
29	US- 5882631		03/16/99	Suga, et al.	
30	US- 5741487		04/21/98	Asai, et al.	
31	US- 6113887		09/05/00	Mori, et al.	
32	US- 4122158		10/24/78	Schmitt	
33	US- 3983209		09/28/76	Schmitt	
34	US- 4885163		12/05/89	Shaar, et al.	
35	US- 6177554		01/23/01	Woo, et al.	
36	US- 6187757		02/13/01	Clackson, et al.	
37	US- 5162226		11/10/92	Beachey, et al.	
38	US- 6335012		01/01/02	Fischetti, et al.	
39	US- 6326002		12/04/01	Fischetti, et al.	
40	US- 6277399		08/21/01	Fischetti, et al.	
41	US- 4062941		12/13/77	Davies	
42	US- 5571667		11/05/96	Chu, et al.	
43	US- 5514602		05/07/96	Brooks Jr, et al.	
44	US- 5500350		03/19/96	Baker, et al.	
45	US- 5384265		01/24/95	Kidwell, et al.	
46	US- 4361537		11/30/82	Deutsch, et al.	
47	US- 5120643		06/09/92	Ching, et al.	

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
48	WO-9323544		11/25/93	The University Court of the University of Glasgow		
49	EP-0293249 A1		11/30/88	Amrad Corporation Limited		
50	EP-0646646 A2		04/05/95	Bristol-Myers Squibb Company		
51	EP-0359873 A1		03/28/90	The Public Health Research Inst. of the City of New York		

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		Number - Kind Code ² (if known)			
	52	US-4948726	08/14/90	Longoria	
	53	US- 4459361	07/10/84	Gefter	
	54	US- 4552839	11/12/85	Gould, et al.	
	55	US- 4313734	02/02/82	Leuvering	
	56	US- 4847199	07/11/89	Snyder, et al.	
	57	US- 4497900	02/05/85	Abram, et al.	
	58	US- 4707543	11/17/87	Zollinger, et al.	
	59	US- 5763251	06/09/98	Gasson	
	60	US- 6159688	12/12/00	Borchert, et al.	
	61	US- 4784948	11/15/88	Scott, et al.	
	62	US- 5760026	06/02/98	Blackburn, et al.	
	63	US- 5602040	02/11/97	May, et al.	
	64	US- 4521252	06/04/85	Miyake, et al.	
	65	US- 4355022	10/19/82	Rabussay	
	66	US- 4115546	09/19/78	Vidra, et al.	
	67	US- 4116327	09/26/78	Eglinton, et al.	
	68	US- 3929994	12/30/75	Hirsch, et al.	
	69	US- 6083684	07/04/00	Gasson	
	70	US- 5360617	11/01/94	Gasson	
	71	US- 5079174	01/07/92	Buck, et al.	

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	82	KH Nasibulini et al; RU-2103991; Composition for treating streptococcal diseases - comprises purified concentrate of streptococcal bacteriophage, solution of quinsosol, dry lanolin, albumin and vegetable oil; XP-002141110	
	83	LD Demidova et al; RU2064299; Cattle mastitis therapeutic preparation - comprises lyso; amidase of specific lytic activity and mono- and di-basic sodium phosphate(s); XP-002141111	

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Examiner Name	PRATS, FRANCISCO CHANDLER	

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No. ¹	T ²
	84	BABENKO et al. Enzymatic lysis of staphylococci in relation to their species and strain properties, 1990, Database Medline Online, US National Library of Medicine, Bethesda, MD, US, Database Accession No. 90297672 XP002170795, abstract only
	85	BARTELL, et al., Origin of polysaccharide depolymerase associated with bacteriophage infection, Journal of Virology, March 1969, pp. 290-296, Vol. 3, No. 3
	86	BEHNKE, et al., Cloning and expression in Escherichia coli, Bacillus subtilis and Streptococcus sanguis of a gene for staphylokinase - a bacterial plasminogen activator, Mol Gen Genet, December 1987, pp. 528-534, Vol. 210
	87	BESSEN, et al., Chemical characterization of binding properties of opacity-associated protein II from Neisseria gonorrhoeae, Infection and Immunity, January 1987, pp. 141-147, Vol. 55, No. 1
	88	BIZIULEVICHUS, et al., In vivo studies on lysobacillin: 3. Efficacy for treatment of mastitis and superficial lesions of the udder and teats in cows, 1998, Database Biosis Online, Biosciences Information Service, Philadelphia, PA, US, Database Accession No. PREV199800492606, XP002183274, abstract only
	89	BOIZET, et al., Cloning, expression and sequence analysis of an endolysin-encoding gene of Lactobacillus bulgaricus bacteriophage mv1, Gene, 2000, pp. 61-67, Vol. 94
	90	CALDWELL, et al., Purification and partial characterization of the major outer membrane protein of Chlamydia trachomatis, Infection and Immunity, March 1981, pp. 1161-1176, Vol. 31, No. 3
	91	YOUNG et al. Phages will out: strategies of host cell lysis, Trends in Microbiology, Volume 8 No. 3, March 2000, pp 120-127
	92	CORBEL, et al., Soluble antigens obtained from influenza virus by treatment with non-ionic detergent, J Hyg. Camb., 1970, pp. 81-96, Vol. 68
	93	CROUX, et al., Interchange of functional domains switches enzymes specificity: construction of a chimeric pneumococcal-clostridial cell wall lytic enzyme, Molecular Microbiology, 1993, pp.1019-25, Vol. 9, No. 5
	94	DIAZ, et al., Chimeric phage-bacterial enzymes: a clue to the modular evolution of genes, Proc. Natl. Acad. Sci. USA, October 1990, pp. 8125-8129, Vol. 87

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	95	DIAZ, et al., Chimeric pneumococcal cell wall lytic enzymes reveal important physiological and evolutionary traits, Journal of Biological Chemistry, March 25, 1991, pp. 5464-5471, Vol. 266, No. 9
	96	DIXON, et al., Lysostaphin: an enzymatic approach to staphylococcal disease. III. Combined lysostaphin-methicillin therapy of established staphylococcal abscesses in mice, The Yale Journal of Biology and Medicine, August 1968, pp. 62-68, Vol. 41, No. 1
	97	FISCHETTI, et al., Size variation of the M protein in group A streptococci, Journal of Exp. Med., June 1, 1985, pp. 1384-1401, Vol. 161, No. 6
	98	GARCIA, et al., Bacteriophages of Streptococcus pneumoniae: A molecular approach, Microbial Drug Resistance, Summer 1997, pp. 165-176, Vol. 3, No. 2
	99	GARCIA, et al., Cloning, purification and biochemical characterization of the pneumococcal bacteriophage Cp-1 lysis, Journal of Virology, August 1987, pp. 2573-2580, Vol. 61, No. 8
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	102	GOLDBERG, et al., Studies in experimental staphylococcal endocarditis in dogs, Antimicrobial Agents and Chemotherapy, 1967, pp. 45-53
	103	HARRISON, et al., Lysostaphin in experimental renal infections, Journal of Bacteriology, February 1967, pp. 520-524, Vol. 93, No. 2
	104	HARRISON, et al., Therapeutic activity of lysostaphin in experimental staphylococcal infections, Canadian Journal of Microbiology, January 1967, pp. 93-97, Vol. 13, No. 1
	105	HAYASHI, et al., Effects of N-Acetyl muramidase from Streptomyces rutgersensis H-46 as a food preservative, Agric. Biol. Chem., December 1989, pp. 3173-3177, Vol. 53, No. 12

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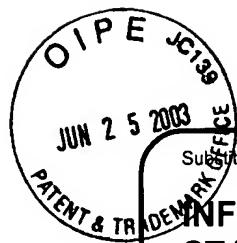
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Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	106	HAYASHIDA, et al., Further characterization of PL-1 phage associated N-acetylmuramidase of Lactobacillus casei, Journal of General Microbiology, May 1987, pp. 1343-1349, Vol. 133, No. 5
	107	HIGUCHI, et al., Transfection of streptococcus sanguis by phage deoxyribonucleic acid isolated from streptococcus mutans, Infection and Immunity, March 1977, pp. 945-949, Vol. 15, part 3
	108	HUAN, et al., Methicillin-resistant staphylococcus aureus infection and its treatment in burned patients, Chinese Journal of Surgery, 1994, Vol. 32, No. 4, abstract
	109	HUGHEY, et al., Antimicrobial activity of lysozyme against bacteria involved in food spoilage and food-borne disease, Applied and Environmental Microbiology, September 1987, pp. 2165-2170, Vol. 53, No. 9
	110	KOHLER, Systemic therapy with aerosols Aerosols in Medicine: Principles, Diagnosis and Therapy, 1993, Elsevier Science Publishers, pp. 303-319
	111	LAWMAN, et al., Molecular cloning of the extracellular endodextranase of streptococcus salivarius, Journal of Bacteriology, December 1991, pp. 7423-7428, Vol. 173, No. 23
	112	LOESSNER, et al., Evidence for a holin-like protein gene fully embedded out of frame in the endolysin gene of staphylococcus aureus bacteriophage 187, Journal of Bacteriology, August 1999, pp. 4452-4460, Vol. 181, No. 15
	113	LOESSNER, et al., Modified listeria bacteriophage lysin genes (ply) allow efficient overexpression and one - step purification of biochemically active fusion proteins, Applied and Environmental Microbiology, August 1996, pp. 3057-3060, Vol. 62, No. 8
	114	LOPEZ, et al., Architecture and domain interchange of the pneumococcal cell wall lytic enzymes, Genetics of Streptococci, Enterococci and Lactococci, Developments in Biological Standardization, 1995, pp. 273-281, Vol. 85
	115	LOPEZ, et al., The pneumococcal cell wall degrading enzymes a modular design to create new lysins, Microbial Drug Resistance, November 2, 1997, pp. 199-211, Vol. 3, No. 2
	116	MARTIN, et al., Functional analysis of the two-gene lysis system of the pneumococcal phage Cp-1 in homologous and heterologous host cells, Journal of Bacteriology, January 1998, pp. 210-217, Vol. 180, No. 2

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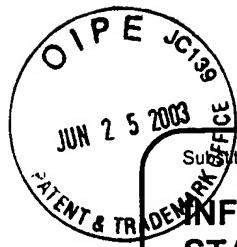
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Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	117	MUKHLIS, et al., Characterization and Immunogenicity of HSV-1 antigens obtained following zwitterionic detergent treatment; Vaccine, September 1986, pp. 191-196, Vol. 4
	118	NELSON, et al., Prevention and elimination of upper respiratory colonization of mice by group A streptococci by using a bacteriophage lytic enzyme, PNAS, March 27, 2001, pp. 4107-4112, Vol. 98, No. 7
	119	NELSON, et al., Selective and rapid killing of group A streptococci using a muralytic enzyme, Database Biosis Online, Biosciences Information Service, Philadelphia, PA, US and abstracts of the General Meeting of the American Society for Microbiology, 2000, pp. 32-33
	120	OKI, et al., Functional and structural features of the holin HOL protein of the Lactobacillus plantarum phage analysis in escherichia coli system, Gene, 1997, pp. 137-145, Vol. 197
	121	OKUHARA, et al., Preparation of group A streptococcal cell membranes by treatment with group C streptococcus phage - associated lysin, Annales Paediatrici Japonici, June 1983, pp. 10-19, Vol. 29, No. 2
	122	PATTON, et al., Routes of delivery: case studies, Pulmonary delivery of peptides and proteins for systemic action, Advanced Drug Delivery Reviews, 1992, pp. 179-196, Vol. 8
	123	POLAK, et al., In vitro activity of recombinant lysostaphin-antibiotic combinations toward methicillin-resistant staphylococcus aureus, Diagn. Microbiol. Infect. Dis., 1993, pp. 265-270, Vol. 17
	124	RAINAS, Purification of streptococcus group C bacteriophage lysin, Journal of Bacteriology, January 1981, pp. 661-663, Vol. 145, No. 1
	125	RONDA, et al., Infection of streptococcus oralis NCTC 11427 by pneumococcal phages, FEMS Microbiology Letters, 1989, pp. 187-192, Vol. 65
	126	SANZ, et al., Construction of a multifunctional pneumococcal murein hydrolase by module assembly, Eur. J. Biochem., February 1, 1996, pp. 601-605, Vol. 235, No. 3
	127	SATO, et al., Partial characterization of n - Butanol - solubilized rejection - type antigens of syngeneic murine colon tumors, JNCI, April 1985, Vol. 74, No. 4

Examiner Signature	Date Considered
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¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

10

of

11

Complete if Known

Application Number	10/067,979
Filing Date	2/8/02
First Named Inventor	Vincent Fischetti
Group Art Unit	1651
Examiner Name	PRATS, FRANCISCO CHAMBER

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	128	SHEEHAN, et al., Analysis of the catylytic domain of the lysin of the lactococcal bacteriophage Tuc2009 by chimeric gene assembling; FEMS Microbiology Letters, 1996, pp. 23-28, Vol. 140	
	129	SHEEHAN, et al., The lytic enzyme of the pneumococcal phage Dp-1: A chimeric lysin of intergeneric origin, Molecular Microbiology, 1997, pp. 717-725	
	130	WITTE, et al., Characterization of escherichia coli lysis using a family of chimeric E-L genes, FEMS Microbiology Letters, 1998, pp. 159-167, Vol. 164	
	131	YARNALL, et al., Isolation and partial characterization of a type II Fc receptor from a group A streptococcus, Molecular and Cellular Biochemistry, 1986, pp. 57-66, Vol. 70	
	132	CISANI, et al., High-level potentiation of lysostaphin anti-staphylococcal activity by lysozyme, Antimicrobial Agents and Chemotherapy, April 1982, pp. 531-535, Vol.21, No. 4	

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¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 11 of 11

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/067,979
		Filing Date	2/8/02
		First Named Inventor	Vincent Fischetti
		Group Art Unit	1651
		Examiner Name	PRATS, FRANCISCO CHANDLER
Sheet	11	of	11
		Attorney Docket Number	

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	133	US-5605793	02/25/97	Stemmer	
	134	US- 6355477	03/12/02	Fischetti et al	
	135	US- 6331405	12/18/01	Rambukkana et al	
	136	US- 6190659	02/20/01	Pancholi et al	
	137	US- 5985654	11/16/99	Fischetti et al	
	138	US- 5842314	11/24/98	Scott et al	JUN 20 200
	139	US- 5910441	06/08/99	Rocha et al	
	140	US- 5786205	07/28/98	Fischetti et al	
	141	US- 5976792	11/02/99	Cheung et al	TECH CENTER 160
	142	US- 5821088	10/13/98	Darzins et al	
	143	US- 5723303	03/03/98	Fischetti et al	
	144	US- 5643767	07/01/97	Fischetti et al	
	145	US- 5707822	01/13/98	Fischetti et al	
	146	US- 5616686	04/01/97	Fischetti et al	
	147	US- 5604109	02/18/97	Fischetti et al	
	148	US- 5587288	12/24/96	Cheung et al	
	149	US- 5556944	09/17/96	Fischetti et al	
	150	US- 5352588	10/04/94	Fischetti et al	
	151	US- 5968763	10/19/99	Fischetti et al	
	152	US- 4784948	11/15/88	Scott et al	

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Appendix A

Serial No.	Filing Date	Patent N .	Issue Date
07/621,716	June 18, 1984	4,784,948	November 15, 1988
09/257,025	February 25, 1999	6,017,528	January 25, 2000
09/257,026	February 25, 1999	5,985,271	November 16, 1999
09/333,538	June 15, 1999		
09/395,636	September 14, 1999	6,056,954	May 2, 2000
09/395,637	September 14, 1999	6,056,955	May 2, 2000
09/482,992	January 14, 2000	6,264,945	July 24, 2001
09/497,495	April 18, 2000	6,238,661	May 29, 2001
09/560,650	April 28, 2000		
09/653,690	September 1, 2000	6,254,866	July 3, 2001
09/654,482	September 1, 2000	6,399,097	June 4, 2002
09/654,483	September 1, 2000	6,423,299	July 23, 2002
09/654,484	September 1, 2000		
09/671,878	September 28, 2000	6,432,444	August 13, 2002
09/671,879	September 28, 2000	6,248,324	June 19, 2001
09/671,880	September 28, 2000	6,406,692	June 18, 2002
09/671,881	September 28, 2000	6,428,784	August 6, 2002
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09/671,992	September 28, 2000	6,335,012	January 1, 2002
09/703,164	November 2, 2000		
09/703,582	November 2, 2000		
09/703,583	November 2, 2000		
09/703,584	November 2, 2000		
09/703,585	November 2, 2000		
09/703,586	November 2, 2000		
09/703,587	November 2, 2000		
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Appendix A

Serial No.	Filing Date	Patent N .	Issue Dat
09/703,686	November 2, 2000		
09/703,739	November 2, 2000		
09/703,740	November 2, 2000		
09/704,148	November 2, 2000		
09/704,149	November 2, 2000		
09/752,731	January 3, 2001		
09/844,435	April 30, 2001		
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09/866,106	May 25, 2001		
09/908,737	July 19, 2001		
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09/960,472	September 21, 2001		
10/012,032	December 11, 2001		
10/067,979	February 8, 2002		
10/067,991	February 8, 2002		
10/067,995	February 8, 2002		
10/083,142	February 27, 2002		
10/083,462	February 27, 2002		
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10/105,076	March 25, 2002		
10/135,824	May 1, 2002		
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10/135,851	May 1, 2002		
10/145,604	May 14, 2002		
10/176,375	June 21, 2002		
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10/219,250	August 16, 2002		

Appendix A

Serial No.	Filing Date	Patent No.	Issue Date
10/219,251	August 16, 2002		
10/252,031	September 23, 2002		
60/324,089	September 24, 2001		
60/380,875	May 17, 2002		